

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,885	10/28/98	CUBICCIOTTI	R BDA-0038

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HM12/0526

 EXAMINER

WARE, T

ART UNIT	PAPER NUMBER
1615	<input type="checkbox"/>

DATE MAILED: 05/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/171,885</b>	Applicant(s) <b>Cubicciotti</b>
	Examiner <b>Todd D. Ware</b>	Group Art Unit <b>1615</b>

Responsive to communication(s) filed on Jan 25, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-8 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3+4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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### **DETAILED ACTION**

Receipt of form 903 filed 12/21/98 and information disclosure statements filed 1/25/99 and 2/1/99 are acknowledged.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing and are therefore rendered indefinite. For purposes of clarity, the property of "binding affinity" should remain either a property of the drug or the receptor. It becomes confusing when it is interchanged. Generally, in the art, binding affinity is a property of the drug and not the receptor. As an example, the examiner suggests amending claim 1 to read, "A prodrug complex comprising: a) a selected synthetic receptor and b) a selected drug that binds to the synthetic receptor with less affinity than a targeted pathophysiologic receptor, such that the selected preferentially binds to the targeted pathophysiologic receptor with no loss of potency and/or efficacy of the selected drug." For purposes of this Office Action, the examiner interprets the claims to read on this suggestion.

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***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morgan, Jr. et al. ('713). '713 reads on drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds non-covalently to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Furthermore, a biologic structure, such as an antibody, may be coupled to this complex and the carriers may bind more than one drug (abstract, and column 1, lines 9-15 and column 2, lines 28-63).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgen, Jr. et al. ('713). '713 teaches drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds non-covalently to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Furthermore, a biologic structure, such as an antibody, may be coupled to this complex and the carriers may bind more than one drug (abstract, and column 1, lines 9-15 and column 2, lines 28-63). The statement, "Drug activity also is preserved in vivo after administration of the conjugate to a human or mammalian host" (column 2, lines 61-63) in '713 teaches that the drug's affinity for the polymeric receptor is less than that for its pathophysiologic receptor. Accordingly, based upon the teachings of '713, it would be obvious to one skilled in the art at the time the invention was made to deliver a drug via a prodrug complex where the drug is bound to a polymeric carrier such that the drug would not dissociate during in vivo administration, but would maintain its activity by preferentially binding to its pathophysiologic receptor over the polymeric carrier with the expected result of reducing the drug's toxicity.

### *Conclusion*

7. Currently, no claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is

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(703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.



THURMAN K. PAGE  
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5/19/99